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# WHEN THE TRUTH IS NOT ENOUGH: TISSUE DONATION, ALTRUISM, AND THE MARKET

Michelle Oberman\*

## INTRODUCTION

One of the most profitable new industries that arose in the late twentieth and early twenty-first centuries derives from the numerous uses identified for human tissue. Taking its cue both from advances in medical transplant technology and also from other successful innovations predicated upon finding new uses for what others have deemed waste,<sup>1</sup> the market in human tissue involves the creative recycling of skin, bone, and other body parts from human cadavers. Over the course of the past twenty years, some participants in this market have realized extraordinary profits.<sup>2</sup>

Although both involve transplantation, the market in tissue transplantation has surprisingly little in common with the organ transplantation industry. Beginning in the 1950s, doctors turned to organ transplants in an effort to prolong the lives of individuals experiencing the failure of major organ systems.<sup>3</sup> By the 1980s, with the advent of

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1. For example, International Mulch Company has transformed more than one million old truck tires into seventeen million pounds of shredded truck tires used for covering playgrounds and garden areas. See *Giving Old Truck Tires a Second Life*, [http://www.baumpub.com/publications/rpn/rpn\\_features/rpn\\_05mar\\_f5.htm](http://www.baumpub.com/publications/rpn/rpn_features/rpn_05mar_f5.htm) (last visited Feb. 22, 2006). In another example, Waste Stream Environmental, Inc. profits by turning human waste into fertilizer. 1998 Governor's Waste Reduction and Recycling Awards, <http://www.dec.state.ny.us/website/dshm/redrecy/98recawd.htm> (last visited Feb. 22, 2006).

2. See Mark Katches et al., *Making Death Pay*, ORANGE COUNTY REG., Apr. 20, 2000, available at <http://www.ocregister.com/features/body/day5.shtml> (describing the various manners in which people are profiting from the tissue industry).

3. See Sean Authurs, Comment, *No More Circumventing the Dead: The Least-Cost Model Congress Should Adopt to Address the Abject Failure of Our National Organ Donation Regime*, 73 U. CIN. L. REV. 1101, 1104 (2005) (discussing the history of organ transplantation).

antirejection therapies, organ transplantation procedures saved thousands of human lives each year.<sup>4</sup> Today, the potential of these procedures to extend human lives is limited largely by the shortage of organs available for transplantation.<sup>5</sup>

In response to this shortage and in an effort to secure fair allocation of this scarce resource, the federal government heavily regulates the organ industry. Steps such as the federal law requiring hospitals to notify local organ procurement organizations of death or imminent death, so that these organizations can arrange to solicit donations from surviving kin, have helped to bolster the supply of available organs.<sup>6</sup> In addition, legislators and policymakers debate the risks and benefits of attempting to enhance the organ supply by permitting direct payments to donors or their families.

There is a rich literature discussing the merits of the various options for increasing the supply of organs available for transplantation, the most controversial of which involve permitting the buying and selling of organs.<sup>7</sup> Although I share the concerns articulated by many who oppose a market solution to the shortage in human organs, particularly to the extent that it would entail paying living donors for their organs, this Article does not address, let alone resolve, this debate.

The ethical dilemmas at the core of the debate over organ selling revolve around the threat such sales pose to the physical and the dignitary well-being of the donors, as well as the indirect consequences to society triggered by the commodification of human body parts.<sup>8</sup> These concerns are far less salient when the context is shifted to the tissue transplantation industry. First of all, the supply of human tissue from cadaver donors, let alone from live donors, is quite ample and is, in any case, far less limited than the supply of human organs.<sup>9</sup> Thus,

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4. See *id.* at 1105.

5. See Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification*, 56 RUTGERS L. REV. 305, 311 (2004) (discussing the inability of the American procurement model to meet the "growing demand for organs needed by the critically ill"). See also United Network for Organ Transplants, <http://www.unos.org/> (last visited Jan. 22, 2006) (giving up-to-date statistics on the number of persons waiting for organ transplants; on January 22, 2006 the site listed 90,689 people awaiting transplants).

6. See 42 C.F.R. § 482.45 (2005).

7. See Goodwin, *supra* note 5. See also Gloria J. Banks, *Legal & Ethical Safeguards: Protection of Society's Most Vulnerable Participants in a Commercialized Organ Transplantation System*, 21 AM. J.L. & MED. 45 (1995).

8. See Banks, *supra* note 7, at 83–97 (discussing various potential consequences of organ selling).

9. See Anne Belli, *Families of Donors Rarely Get Full Story*, HOUS. CHRON., Feb. 13, 2005, available at 2005 WLNR 2037184. Belli noted that "[b]ecause tissue from a donor's body can be recovered up to 24 hours after death if it is refrigerated, a far greater number of people are potential tissue donors. And because so many tissues can be recovered from a body, dozens of

there is less risk that market incentives necessarily will lead to exploitation and overreaching. Second, even if one seeks to retrieve tissue from live donors for purposes of transplantation, such retrievals seldom carry with them the permanent threat to the donor's health and well-being experienced by those who sacrifice an organ.<sup>10</sup> At the risk of oversimplification, my point is merely that skin will regenerate; a kidney will not. Most importantly, other than the similarity of the fact that the raw materials employed come from human bodies, the tissue industry is almost completely unlike the organ industry.

As described in detail in Part II of this Article, the world of tissue transplantation is relatively invisible and largely unregulated in contrast to the organ transplantation industry. This invisibility may be attributed to several distinguishing factors. First, donated tissue is put to far less glamorous uses than are donated organs, and as such has not garnered public attention. With perhaps a few narrow exceptions (e.g., heart valves), donated tissue is not used in any life-saving procedures.<sup>11</sup> Instead, transplanted human tissue is used overwhelmingly for "life-enhancing" procedures. For example, skin retrieved from human cadavers can be processed into products that are used in treating burn victims or for cosmetic purposes such as enhancing lip size, reducing wrinkles, or enlarging penises.<sup>12</sup> Bones can be ground into powder and processed for use in repairing the bones and teeth of living individuals.<sup>13</sup>

Second, unlike the situation with human organs, there is at present no shortage of human tissue. Tissue donation is approximately three times as common as organ donation—a reality that is dictated, at least in part, by the fact that there are so many more potential tissue donors

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transplantations can result." *Id.* Tissue banks are able to recover tissue for fifty to one hundred patients from a single cadaver. Mark Katches et al., *Donor's Don't Realize They Are Fueling a Lucrative Business*, ORANGE COUNTY REG., Apr. 16, 2000, available at <http://www.ocregister.com/features/body/day1.shtml>. Tissue bank leaders also use human remains to create new products, such as small pieces of crafted bone, which cost about 2,000 dollars a piece. Mark Katches, *Body Parts Good as Gold for Largest Nonprofit Tissue Bank*, ORANGE COUNTY REG., Apr. 16, 2000, available at [http://www.ocregister.com/features/body/day1\\_knox.shtml](http://www.ocregister.com/features/body/day1_knox.shtml).

10. See Bryan Shartle, *Proposed Legislation for Safely Regulating the Increasing Number of Living Organ and Tissue Donations by Minors*, 61 LA. L. REV. 433, 436 (2000–2001) (explaining that live tissue donors experience fewer risks than live organ donors because tissue donors usually donate regenerative tissue such as "blood, ovum, skin, bone marrow, and sperm").

11. See Robert A. Katz, *The Re-Gift of Life: Can Charity Law Prevent For-Profit Firms From Exploiting Donated Tissue and Nonprofit Tissue Banks?*, 55 DEPAUL L. REV. 943, 963 (2006) (discussing the use of heart valves in treating patients with defective heart function).

12. See *id.* at 965–66.

13. See Osteotech Corporate Overview, <http://www.osteotech.com/corpoever.htm> (last visited Sept. 21, 2005).

than potential organ donors.<sup>14</sup> Thus there is little need for regulation to ensure an abundant supply of tissue. Indeed, as discussed in Part II.A., the absence of regulation has most definitely contributed to the abundance of this supply, as those who solicit tissue have not, to date, been required to disclose the manner in which donated tissue will be used.

In addition to the distinctions between the end uses of transplanted tissue and organs, there are major differences in the process by which human tissue is rendered transplantable. Whereas organs typically move quickly from donor to recipient, requiring little or no processing, human tissue often passes through many third parties prior to transplantation. As Part II.B. explains, each of these third parties is compensated—often with significant profit margins—for the role it plays in rendering the tissue ready for transplantation.<sup>15</sup>

The relatively low profile of the tissue transplantation industry is destined to change, if only because the regulatory vacuum has given rise to several notorious scandals involving various players in the industry.<sup>16</sup> In the spring of 2005, the federal government set about remedying these problems by proposing regulations to govern the solicitation of human tissue from the decedant's surviving family members.<sup>17</sup> The foundation of these new federal regulations is the belief that mandating greater disclosure by those who solicit donations will insulate families from the risks of exploitation.<sup>18</sup>

This Article argues that these regulations, as drafted, offer too little protection to families, and in addition, generate a threat to the entire organ and tissue transplant industry. I therefore argue instead that the federal government must encourage states to establish distinct

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14. See Belli, *supra* note 9; see also Katches et al., *supra* note 9 (explaining that tissue donation is more prevalent than organ donation because “[o]rgans can only be harvested from donors who are brain dead but whose heart and other organs are still functioning” whereas “[t]issue still can be recovered” within twenty-four hours after death).

15. See *infra* Part II.B.

16. See, e.g., Bob Meadows et al., *Gang of Ghouls: After Cops Smash a Body-Parts-For-Sale Ring, a New Fear: Did Surgery Patients Get Tainted Human Tissue?*, PEOPLE MAG., Mar. 13, 2006, at 117 (discussing an alleged conspiracy involving a Brooklyn funeral home and a New Jersey-based tissue processing agency's lucrative practice of removing bones and tissues from cadavers, including those of famed British reporter Alistair Cooke, without consent from the family of the deceased). See also *Hartt v. County of Los Angeles*, No. B158539, 2003 WL 22725692 (Cal. Ct. App. Nov. 20, 2003) (refusing to grant relief to a family whose deceased son's cornea and lungs were donated by the coroner's office without permission from the family); see also ANNIE CHENEY, *BODY BROKERS: INSIDE AMERICA'S UNDERGROUND TRADE IN HUMAN REMAINS* (forthcoming 2006).

17. 70 Fed. Reg. 6086 (proposed Feb. 4, 2005) (to be codified at 42 C.F.R. pt. 486.342).

18. *Id.* at 6111 (discussing the need to take certain steps in order to ensure that families are fully informed before making the decision to donate).

mechanisms for securing consent for tissue retrieval from competent individuals prior to death, and also must permit organ procurement agencies to offer families fixed compensation in exchange for human tissue. There is little to be feared from the introduction of such payments into the market in tissues. To the contrary, a host of legal and ethical justifications work to transform what is a hard question in the context of the market in human organs to a rather obvious answer in the context of transactions in human tissue.

Part II of this Article begins with a brief overview of the tissue industry, describing the nature of the procurement process as well as the end uses of the tissue collected from human cadavers.<sup>19</sup> Following this, I turn to a critical analysis of the proposed federal regulations, demonstrating the multiple ways in which they both fail at their task of protecting families and pose a significant risk to the vitality of the market in human tissue.<sup>20</sup> My analysis exposes the legal constraints that frame this industry, including issues ranging from private tort and contract law to constitutional law principles such as First Amendment concerns and autonomy rights. The final section turns to the problem of regulating this industry, particularly the procurement process.<sup>21</sup> I propose that the solicitation of human tissue, unlike that of human organs, should be treated as a market transaction in which families are offered compensation in exchange for providing access to their loved ones' remains.

## II. THE TISSUE INDUSTRY TODAY

Tissue "donation" is surprisingly big business in light of its relatively low profile.<sup>22</sup> The number of uses for human tissue, and the frequency

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19. Tissue can be retrieved from live donors, as well as from cadavers. See Barbara Indech, *The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue Banking in Select Countries and the Current State of International Harmonization Efforts*, 55 FOOD DRUG L.J. 343, 343 (2000). Tissue donations from cadavers raise more complex issues because of the need to obtain consent from the family, rather than from the donor.

20. See *infra* Part III.

21. See *infra* Part IV.

22. The term "donation" is somewhat of a euphemism in that there is a long-standing, if sporadic, record of the use of human body parts and tissues without consent. Historically, one sees evidence of this in the practice of "cadaver snatching," in which predominantly African-American bodies were appropriated for medical study. See Goodwin, *supra* note 5, at 376-81. Today, the term "donation" is rendered an oxymoron in state laws permitting the "mandatory donation" of corneas from cadavers. See *Brotherton v. Cleveland*, 923 F.2d 497, 477 (6th Cir. 1991), for a successful challenge to these practices on due process grounds. See also Erik S. Jaffe, Note, "She's Got Bette Davis[s] Eyes": Assessing the Nonconsensual Removal of Cadaver Organs Under the Takings and Due Process Clauses, 90 COLUM. L. REV. 528, 550 n.106 (1990) (discussing the history of property rights in cadavers).

of such use, is growing exponentially. In 1990, there were 350,000 musculoskeletal transplantations using human tissue.<sup>23</sup> By 2002, that number was over 800,000.<sup>24</sup> The following section discusses the process by which tissue is procured and rendered, and provides an overview of the tissue industry.

### A. *The Process of Tissue Procurement and Rendering*

Unlike organs, tissue can be recovered from almost any corpse up to twenty-four hours after death.<sup>25</sup> Thus, a far greater number of people are potential tissue donors than organ donors. Also, because so many different tissues can be recovered, each corpse represents scores of potential uses. Federal law governing organ transplantation helped to expand the supply of available tissue by requiring hospitals to notify the regional Organ Procurement Organization (OPO) in the event of a potential donor's death.<sup>26</sup> By making requests for donation routine, these regulations had the indirect effect of enhancing the availability of tissue, as well as organs.

Although the law does not require it at the present time, only non-profit agencies are engaged in soliciting and retrieving tissue from human cadavers.<sup>27</sup> For the most part, hospitals have delegated the solicitation process to OPO agents, who are specially trained to work with families under these challenging circumstances.<sup>28</sup> Solicitation may take place either in person—typically at the hospital—or by telephone.<sup>29</sup> Either way, solicitation must occur quickly, as the tissue must be retrieved no later than twenty-four hours after death.

If the next of kin agree to donate, the OPO arranges for the tissue to be recovered. Many OPOs operate as tissue banks and thus, in addition to their work in recovering and transferring organs, are

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23. *Tissue Banks: The Dangers of Tainted Tissues and the Need for Federal Regulation: Hearings Before the S. Comm. on Governmental Affairs*, 108th Cong. 2 (2003) (statement of Jesse L. Goodman, Director, Food and Drug Administration Center for Biologics Evaluation and Research), available at <http://hsgac.senate.gov/051403goodman.pdf>.

24. *Id.*

25. Belli, *supra* note 9.

26. 42 U.S.C. § 1320b-8(a)(1) (2000); 42 C.F.R. § 482.45 (2005). The regulations were expanded and updated in 1998, from simply informing families of the option to donate, to actually requiring hospitals to notify the OPO, which then makes a request for donation.

27. Telephone Interview with Thomas Mone, Chief Executive Officer, OneLegacy (Mar. 30, 2005).

28. Telephone Interview with Edward Goldman, Associate Vice President and Deputy General Counsel, Office of the General Counsel Health System Legal Office, University of Michigan (Feb. 23, 2005).

29. Telephone Interview with Thomas Mone, *supra* note 27.

equipped to retrieve and store human tissue.<sup>30</sup> Others work with independent tissue banks, which will be notified of the family's consent and will undertake the retrieval process.<sup>31</sup> Tissue retrieval can be costly, as it requires not only the proper procedures for removing and preserving the tissue but also the work of restoring the appearance of the corpse.<sup>32</sup>

Following the removal of the tissue, the OPO will transfer the tissue to a tissue processor, which will prepare the tissue for use by others, whether for transplantation or for creation of a commercial product such as AlloDerm.<sup>33</sup> The OPO will charge the tissue processor a "reasonable payment" designed to reflect the OPO's costs in retrieving and storing the tissue. These costs vary significantly—"[a] typical donor produces \$14,000 to \$34,000 in sales for the nonprofits . . . ."<sup>34</sup>

When treated and rendered transplantable by the tissue processors, this same raw material will gain enormous value. For example, "[s]kin, tendons, heart valves, veins and corneas are listed at about \$110,000. Add bone from the same body, and one cadaver can be worth about \$220,000."<sup>35</sup> These gains are realized when the tissue processors distribute the tissues to doctors, hospitals, or other users of their end products. Given these stakes, it was perhaps inevitable that the symbiotic relationship between nonprofit and for-profit agencies dealing in human tissue would generate some instances of abuse. The following subsection describes the tissue industry and details some of the problems that have resulted from the absence of regulation.

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30. *Id.* Mone recommends that OPOs develop their own tissue banks, as OneLegacy has done, so that they can "control the process, not leaving it to small rogue agencies." *Id.*

31. *Id.*

32. See Robert Ninker, *Organ Donations: Should Funeral Directors Encourage It, and Should They Be Reimbursed?*, DEATH CARE BUS. ADVISOR, June 12, 1997. Ninker discussed the painstaking process of putting a body back together after organ and tissue retrieval:

Now we get to the funeral director, who really hasn't been a full partner in the sharing of the costs for organ and tissue transplants. In fact, it is the funeral director who is faced with the huge challenge of restoring a body that has had liberal donations taken from it—donations that can very well include skin, the mandible, back bones, and long bones. When a fully harvested body comes to the preparation room, the embalmer is looking at anywhere from an additional two to 12 hours of work in order to properly restore the remains so that they can be viewed at a visitation. The last thing the organ donor organizations want is for the funeral director to charge the family for any additional work. They feel the family shouldn't have to incur any of the costs associated with the donation, but frequently don't want to reimburse the funeral director in any adequate way.

*Id.*

33. *Id.*

34. Katches et al., *supra* note 9.

35. *Id.*



### B. Overview of the Tissue Industry

There are myriad uses for tissue retrieved from human cadavers. Skin grafts can be used to treat burns or can be processed into products that are useful for cosmetic purposes such as enhancing lip size, reducing wrinkles, or enlarging penises.<sup>36</sup> Bones can be used in transplantation procedures or may be processed and “[u]sed in spinal fusions, to replace cancerous tissue, fill voids caused by trauma, [and] augment prostheses . . . .”<sup>37</sup> Heart valves and arteries may be transplanted.<sup>38</sup> Whole cadavers may be used in the training of doctors at all levels of the profession.<sup>39</sup> The list goes on and grows longer as technology and ingenuity move forward.

The tissue industry is remarkably unregulated, with all manner of participants engaged in the buying and selling of human tissue. There is one major caveat, however: federal law prohibits “any person” from receiving “valuable consideration” in exchange for transferring organs and tissues.<sup>40</sup> The law does acknowledge the costs entailed by tissue retrieval, storage, rendering, and transplantation, and permits those involved in these practices to charge “reasonable payments” to recipients as the tissue moves from one handler to the next.<sup>41</sup>

Thus, although the family members of donors are prohibited from receiving payment in exchange for permitting access to their loved ones’ tissues, every other entity involved in the tissue industry, including the ultimate consumer, pays for access to that tissue. Nor does the law’s ostensible cap on costs (reasonable costs) necessarily dictate that only fixed, modest sums of money change hands. Indeed, the amount of compensation paid for human tissue will vary quite dramatically

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36. See Katz, *supra* note 11, at 965–66.

37. See Osteotech Corporate Overview, <http://www.osteotech.com/corpovert.htm> (last visited Sept. 21, 2005).

38. See Katz, *supra* note 11, at 960.

39. The use of cadavers for training purposes remains unregulated due to the government’s failure to regulate nontransplant tissue banks. Virtually anyone can set up a trade in cadavers so long as that person does not harvest body parts for transplant. Without any federal regulation, families who donate their loved ones’ bodies are almost never informed that the bodies are sold to middlemen or parceled out to surgical equipment companies. See Annie Cheney, *The Resurrection Men: Scenes From the Cadaver Trade*, HARPER’S MAG., Mar. 2004, at 45 (discussing how the federal government’s failure to regulate nontransplant tissue banks has lead to a cadaver market in which bodies are dismembered and sold for medical school research and physician training courses that take place in hotels around the nation). See also Ronald Campbell et al., *Rough Research*, ORANGE COUNTY REG., Apr. 18, 2000, available at <http://www.ocregister.com/features/body/day3.shtml> (discussing how bodies donated for science “are replacing crash-test dummies and animals in sometimes-bizarre research projects”).

40. National Organ Transplant Act (NOTA), 42 U.S.C. § 274e(a) (2000).

41. *Id.* § 274e(c)(2).

according to market considerations.<sup>42</sup> The result is that the tissue industry is definitively—indeed fabulously—profitable, generating an estimated one billion dollars per year.<sup>43</sup>

The potential for profit has contributed to a variety of questionable practices. For example, the close working relationship between non-profit and for-profit agencies dealing in human tissue has led suppliers to favor more regular buyers, or those able to reimburse at higher rates, over others.<sup>44</sup> Thus, burn units complain of a shortage of skin available for transplantation, in spite of the fact that private plastic surgeons enjoy an ample supply for their elective surgeries.<sup>45</sup>

Perhaps more disturbing is the recent spate of thefts reported by families who discovered that their deceased relatives' tissue had been stolen and sold for profit. The media has reported several instances in which funeral parlors allegedly sold bones and other tissue to tissue banks without having secured the permission of surviving family members.<sup>46</sup> The Funeral Ethics Organization, founded in the fall of 2004, devoted the cover story of its first newsletter to the topic of the unregulated trade in body parts.<sup>47</sup> The article's tone is quite revealing regarding the lack of constraints placed upon these key players in the

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42. See Katz, *supra* note 11, at 980–84. Katz notes that the same tissue can be put to different uses, some of which are more lucrative than others. See generally *id.* For example, processors can charge surgeons four times more for skin products than they charge to burn centers. See Katches et al., *supra* note 9.

43. The extent of profits now generated through the use of a product seemingly protected from exploitation under federal law can be seen by considering the example of AlloDerm, the leading product made by LifeCell, Inc. LifeCell is a for-profit corporation that developed AlloDerm in 1992 in order to help reconstruct burn victims' skin following skin grafts. By the late 1990s, this product had been adopted for widespread use not only in the treatment of burn victims but also for use by cosmetic surgeons. The latter clientele is capable of paying far greater sums of money for AlloDerm and generates ten times the level of revenue as burn centers. William Heisel et al., *Lives on the Line*, ORANGE COUNTY REG., Apr. 17, 2000, available at <http://www.ocregister.com/features/body/day2.shtml>. Industry analysts pay tribute to the extraordinary profitability of LifeCell's stock, attributed to the demand for AlloDerm. They note that by 2005, AlloDerm accounted for seventy-five percent of LifeCell's sales; less than ten percent of which went to treating burn victims. BI Research, LifeCell Corp., <http://www.biresearch.com/sample0505.html> (last visited Mar. 28, 2006). In 2005, AlloDerm earned \$93.3 million; its projected earnings for 2006 are between \$124 and \$130 million. HealthpointCapital, LifeCell Reports Preliminary 4Q:05 Financials, [http://www.healthpointcapital.com/research/2006/01/26/lifecell\\_reports\\_preliminary\\_4q05\\_financials/index.php](http://www.healthpointcapital.com/research/2006/01/26/lifecell_reports_preliminary_4q05_financials/index.php) (last visited Mar. 28, 2006).

44. See generally Heisel et al., *supra* note 43.

45. See *id.* (explaining that skin is in high supply for plastic surgeons because they are willing to pay the going rate and they are always buying). Skin for burn victims is in short supply due to the smaller marketplace and a lower profit margin. *Id.* The potential revenue from providing skin for burn victims is estimated at one tenth of the plastic surgery market. *Id.*

46. Meadows et al., *supra* note 16. See also *Hartt v. County of Los Angeles*, No. B158539, 2003 WL 22725692 (Cal. Ct. App. Nov. 20, 2003); CHENEY, *supra* note 16.

47. See Lisa Carlson, *Body Parts: An Unregulated Business*, in FUNERAL ETHICS ORGANIZATION (Fall Newsletter, 2004), available at <http://www.funeralethics.org/fall-04.pdf>.

market in human tissue. For instance, after discussing the existence of a black market in human tissue, it asks whether it is an ethical dilemma for a funeral director to “accept a commission, a finder’s fee or a ‘donation’” in exchange for procuring human tissue.<sup>48</sup> Although the negative ethical and policy implications of engaging in such a practice are self-evident, the author did not attempt to answer this apparently challenging ethical dilemma.

A less sensational yet arguably broader and more problematic consequence of the lucrative nature of the market in human tissue has been the emergence of a variety of alliances and exclusive partnerships between for-profit tissue processors and nonprofit tissue banks in order to stabilize or increase their supply needs.<sup>49</sup> These partnerships allow nonprofit agencies to produce private lines of tissue for the specific purpose of processing, marketing, and distributing the product under for-profit labels.<sup>50</sup> In the most disturbing instances, for-profit tissue processors are actually establishing nonprofit tissue supply banks.<sup>51</sup> For example, RTI, a for-profit tissue processor, formed RTI Donor Servies, Inc., a non-profit tissue bank. This network of interconnected relationships obscures the lines between nonprofit and for-profit tissue agencies.<sup>52</sup>

A word about the distinction between nonprofit and for-profit entities is in order here. Although all OPOs are organized as nonprofit businesses, tissue processors may be either nonprofit or for-profit entities.<sup>53</sup> The line between nonprofits and for-profit entities, however, should not be overstated. The distinction between nonprofit and for-profit is little more than semantic when it comes to the existence of a market, complete with profit incentives, in human tissue. As Professor Julia Mahoney noted:

Refusing to employ the language of commerce disguises the fact that when human tissue is transferred from a lower value user to a higher value user, additional value is created. Such transfers will result not only in invaluable medical treatment and ground breaking research, but also in economic benefits to whatever entities are em-

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48. *Id.* at 1.

49. See Katz, *supra* note 11, at 961–65. See also Katches et al., *supra* note 9.

50. See Katz, *supra* note 11, at 967. For example, Allosource, a nonprofit, produces a private line of products for Interpore Cross International, a for-profit medical device company. *Id.*

51. See *id.* at 1225.

52. See generally Katches et al., *supra* note 9. For a thorough discussion of the nature of this phenomenon and the challenges for those seeking to design appropriate legal regulations for the relationships between the nonprofit and the for-profit sectors of the tissue industry, see Katz, *supra* note 11.

53. See Katz, *supra* note 11, at 944.

powered to capture the surplus. This is true whether the institutions involved are for-profit firms or nonprofit institutions.<sup>54</sup>

To be sure, for-profit businesses are structured with the goal of generating profit, and toward that end, they have owners who exercise varying degrees of control over the enterprise and who are entitled to a share in the revenue it produces. Nonprofit firms do not have owners, nor do those who help to run these businesses receive a share of the firm's net revenue.<sup>55</sup> That being said, it is also true that "[m]any nonprofit firms, including many that provide health care services, engage in profit-making activities and are operated to maximize revenue, while numerous for-profit firms make charitable contributions. In a number of sectors of the economy, including healthcare services, nonprofit and for-profit firms coexist and compete."<sup>56</sup>

In the context of the human tissue industry, the line between nonprofit and for-profit entities is particularly nebulous. This blurriness is due to the overlapping, or even incestuous, alliances forged between nonprofit and for-profit tissue-banking and processing agencies. In part, these alliances help to secure a stable supply for those who draw upon the human tissue industry. For instance, tissue banks might have contracts with for-profit entities because the nonprofit institutions, such as burn centers, have irregular and sporadic needs for tissue.<sup>57</sup> The tissue bank therefore sells tissue to both entities, simply charging more money to the for-profit firms who seek tissue for elective, cosmetic enhancement procedures, and less money to burn units.<sup>58</sup>

### III. MOVEMENT TOWARD REGULATION: THE DISCLOSURE SOLUTION

The growing publicity surrounding the increasing abuses of the human tissue trade has highlighted the need for greater regulation of the tissue industry.<sup>59</sup> At first, many within the tissue industry resisted the call for regulation.<sup>60</sup> They noted that the most egregious of abuse cases involved only a few rogue players within the industry<sup>61</sup> and ex-

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54. Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 192-93 (2000).

55. David A. Shevlin, *Threshold Issues in Forming or Reorganizing a New York Not-For-Profit Organization*, in ADVISING NONPROFIT ORGANIZATION (PLI Tax L. & Estate Planning, Course Handbook Series No. 2783, 2004) (defining nonprofits as "organization[s] organized under the applicable state law as a corporation, trust or unincorporated association for purposes other than distributing income and profits to private owners").

56. Mahoney, *supra* note 54, at 193 n.122.

57. See Heisel et al., *supra* note 43.

58. *Id.*

59. See, e.g., *supra* note 16 and accompanying text.

60. Telephone Interview with Thomas Mone, *supra* note 27.

61. *Id.*

pressed concern that the solution of requiring greater disclosure to families at the point of solicitation would have negative consequences for the entire industry.<sup>62</sup> In essence, they made two justifications for the status quo. First, in the aftermath of the death of a loved one, families were too traumatized to take in a full disclosure regarding the corporate organization and possible downstream uses of tissue. The moment of solicitation was, in short, the wrong time to be informing families of the fact that some small percentage of the tissue they donate might ultimately be processed by for-profit entities who would sell the products they made from it for use in cosmetic procedures.<sup>63</sup> Their second concern was that, to the extent that families were fully informed, they would be less willing to donate.<sup>64</sup> Therefore, the imposition of disclosure requirements threatened the viability of the entire organ and tissue transplant industry.

The federal government was not persuaded by these concerns, and in February 2005 it proposed regulations mandating that donors be given the opportunity to make an "informed consent" to donation.<sup>65</sup> Under the heading "Informed Consent," the proposed regulations provide:

[T]his section would require that an OPO have a written protocol to ensure that the individual(s) making the donation decision for each potential organ donor is informed of their options to donate organs and tissues . . . . The OPO would have to provide to the individual(s) making the donation decision, at a minimum, the following:

- (1) A list of the organs, tissues, or eyes to be recovered,
- (2) All possible uses for the donated organs and/or tissues,
- (3) The information that the individual(s) have the right to limit or restrict use of the organs or tissues,

. . . .  
(5) Information (such as profit or non-profit status) about organizations that will recover, process, and distribute tissue . . . .<sup>66</sup>

The disclosure solution inherent in these proposed regulations presupposes a clarity and consensus about the problem with nondisclosure. In actuality, one might identify at least three aspects of nondisclosure in the present, unregulated solicitation process. First,

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62. See Katches et al., *supra* note 9. Leaders in the tissue industry say that "donations would plummet if families" were informed about the profitable market for donated tissue. *Id.* Jan Pierce, Director of the Intermountain Tissue Center, stated frankly: "If donors were told at the time about profits, they wouldn't donate . . . ." *Id.* (internal quotation marks omitted).

63. Telephone Interview with Thomas Mone, *supra* note 27.

64. *Id.*

65. See Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs), 70 Fed. Reg. 6086, 6119 (proposed Feb. 4, 2005) (to be codified at 42 C.F.R. pt. 486.342).

66. *Id.*

the most obvious nondisclosure problem lies in the fraudulent claims made by those who assure donors that their loved ones' tissue will be used for "medical" or "life-saving" purposes. Such assurances are misleading at best, as they omit reference to the use of donated tissue in purely elective cosmetic procedures. The proposed regulations would guard against this most blatant fraud. But the risks of fraud in the solicitation of tissue go well beyond this narrow concern, as is recognized by the scope of these proposed regulations.

A broader risk of fraud lies in the problem of delineating the possible end uses of donated tissue. For instance, one might believe that cosmetic surgery is a relatively frivolous endeavor and that donors might be disinclined to make a gift of their loved ones' tissue if they knew that it would be used to enhance the puffiness of someone's lips or penis. Thus, the proposed regulations require disclosure of "[a]ll possible uses" for the donated tissue.<sup>67</sup>

A third nondisclosure concern pertains to the monetary gains associated with a tissue's use. Unlike donated organs, donated tissue likely will pass through the hands of several agencies en route to its use in transplantation.<sup>68</sup> Some of these agencies may operate on a for-profit basis, generating considerable revenue.<sup>69</sup> The government demonstrates its awareness of this risk by proposing the disclosure of the for-profit or nonprofit status of all recipient organizations.<sup>70</sup>

Given that the proposed regulations reveal the government's awareness of and concern with a much broader set of nondisclosure risks than those triggered by misleading donors into believing that the tissue will save lives, it is vital to question the extent to which these regulations, as drafted, are likely to accomplish the government's goal of fully informing donors about the nature of the gift that they are asked to make. In the following section, I will explain why the proposed regulations fail to meet the goals of a full and meaningful disclosure. Furthermore, I will explore the regulatory challenge inherent in the goal of creating such disclosure, including First Amendment limitations, and the likely market implications of a more robust disclosure.

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67. *Id.* at 6111.

68. See Katz, *supra* note 11, at 959–60 (discussing the tissue retrieval and processing procedure).

69. See generally Katches et al., *supra* note 9.

70. See 70 Fed. Reg. at 6119.

## IV. WHY THE TRUTH IS NOT ENOUGH

The proposed federal regulations requiring specific disclosures by those soliciting donations of tissue from the families of the deceased mark an important step toward remedying what is a persistent threat, if not a commonplace practice—fraud. Specifically, donor families are defrauded when those soliciting tissue vaguely suggest that a donation would “save or enhance lives” without adding that it might just as easily be sold to a for-profit corporation and used in cosmetic surgery.<sup>71</sup> My concern is that, for a host of reasons, mere disclosure is not enough to remedy the family’s vulnerability to exploitation by solicitors of human tissue donations. Moreover, there is a considerable risk that disclosure, by itself, will have a negative impact on the entire organ and tissue industry, chilling the willingness to donate, and thus constricting an already limited supply of organs and tissue.

The following section will identify and elaborate on four concerns that highlight the residual vulnerability of donor families and the additional problems generated for the organ and tissue industry under the current disclosure regulations. First, I will discuss the First Amendment tensions that may preclude the law from mandating a truly full disclosure. Second, I will note the potential threat that disclosure, whether full or partial, poses to the organ and transplant industry’s ability to cultivate the public’s trust. Third, I will discuss the barriers that may hinder the development of an efficient market response to the problems that are likely to be generated in the wake of greater disclosure. Finally, I will explore the legal considerations, both substantive and procedural, that render problematic, if not unconscionable, the agreements made between families and OPO agents.

*A. The First Amendment and the Regulation of Charitable Solicitations: How Much Truth Will Donors Receive?*

It seems obvious that organ procurement agents should be required to make a full disclosure of their status and of the possible uses to which donations of human tissue may be put when soliciting donations from families of the deceased. Yet making the law conform to this expectation is surprisingly challenging because two lines of cases trigger concerns relevant to the act of regulating the solicitation of donations. The first are cases protecting the charities’ First Amendment

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71. See Katches et al., *supra* note 9 (“Families are led to believe they are giving the gift of life. They are not told that skin goes to enlarge penises or smooth out wrinkles, or that executives of tissue banks . . . routinely earn six-figure salaries. The products are rarely life-saving as advertised.”).

rights to free speech, and the second are cases protecting vulnerable individuals from predatory behavior by limiting the time, place, and manner of solicitation. Once one situates tissue solicitation at the intersection of these two well-established legal concerns, it is relatively easy to see why the proposed regulations require disclosure. I therefore begin this section with a brief discussion of how the law should regard the role played by organ procurement agents in soliciting tissue donations.

### 1. *The Organ Procurement Agent as Solicitor*

Perhaps the biggest obstacle to requiring full disclosure in tissue solicitations stems from the manner in which those working in the tissue industry see and successfully portray themselves to others. Despite the fact that organ procurement agents (those who solicit donations) work on behalf of the organ and tissue procurement industry, they do not necessarily view themselves as agents for this industry.<sup>72</sup> This has led to some confusion about the nature and the extent of disclosure that they should make.

Organ procurement agents have a job that is rife with emotional challenge. They have the difficult task of approaching grieving families to request that they donate parts of their loved ones' bodies to others. The agents never really see or meet the "fruits" of their labor—the recipients of the donated organs or tissue who are thereby permitted the chance to live fuller, healthier, and in some cases, longer lives. Their training focuses heavily on cultivating the appropriate manner in which to solicit the families of the deceased. It is therefore not surprising that these agents view themselves as working on behalf of these families as the families move into the process of mourning. Indeed, as Thomas Mone, the CEO of OneLegacy, the nation's largest OPO, commented:

The OPO staff does feel that they're there first for the donor's family. Fifty of the nation's fifty-eight OPOs are not tied to transplant centers. The staff never sees recipients; indeed, they spend all of their time with donors, hospital staff, and families in hospitals. Partly this is for strategic reasons, but also it is because of their desire to help something good come out of tragedy. It's not all about the recipients . . . . This is what drives the personalities of these folks.<sup>73</sup>

The federal regulations embrace the notion that the agents who solicit organ and tissue donations are somehow acting on behalf of the

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72. Interview with Thomas Mone, *supra* note 27.

73. *Id.*



donor families. The subtitle for this section of the regulations reads "Informed Consent."<sup>74</sup> Informed consent is a doctrine borrowed from the context of medical treatment, wherein a doctor must act as a fiduciary for his or her patient, helping to guide the patient in making treatment decisions.<sup>75</sup> It is a reflection of the reality that patients lack the information they need to make their own treatment decisions, and as such, must rely upon their doctors to look out for their best interests. Informed consent is the hallmark of what differentiates the doctor-patient relationship from a standard arm's length transaction in which both parties are free to act in their own self-interest.<sup>76</sup>

The informed consent paradigm is misplaced in the context of the solicitation of human tissue. There are no fiduciaries in transactions involving the solicitation of human tissue from families of the deceased. No matter how sensitively they solicit donations, OPO agents are just that—employees of the OPO. These agents are not fiduciaries for the families of the deceased. Even if their solicitations occur in the hospital, gaining a family's consent to a donation is not akin to gaining a patient's consent to treatment. Doctors obtain informed consent from their patients, disclosing the risks and benefits of a proposed course of action, because their patients have no other choice but to rely upon them as fiduciaries. There is no similar reliance between the OPO agent and the bereaved family. Quite the contrary—the OPO's loyalties do not lie with the family. The OPO agent is employed by the OPO for the purpose of securing gifts from family members. They are fundraisers, soliciting a donation for their organizations.<sup>77</sup>

The more appropriate framework for conceptualizing the relationship between the OPO agent and the family of the deceased is that of charitable solicitations. The OPO agent, acting on behalf of a non-profit charitable organization, approaches the family with a request for a donation. Although there are important ways in which the solicitation of tissue donations differs from the more typical, charitable solicitation of financial support, generally speaking the relationship between the OPO agent and the donor's family fits squarely within

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74. See 70 Fed. Reg. at 6119.

75. Michelle Oberman, *Mothers and Doctors' Orders: Unmasking the Doctor's Fiduciary Role in Maternal-Fetal Conflicts*, 94 Nw. U. L. Rev. 451, 455–56 & n.19 (2000).

76. See *id.*

77. Those who care for the dying—perhaps the most familiar with the solicitation process—tell of some OPO agents who hover near the doors of the hospital rooms of dying patients, waiting for the chance to solicit organ and tissue donations from family members. Interview with Margaret Eaton, Senior Research Scholar, Stanford Center for Biomedical Ethics (Dec. 5, 2005). Clearly, such behavior is not consistent with the notion of fiduciary duty.

the framework of solicitation for charitable purposes. As such, it is important to understand the extent to which the law regulates such solicitations and the reasons why the law likely will preclude the government from demanding rigorous disclosure by OPO agents.

## 2. *The Regulation of Charitable Solicitations: The "Trilogy" and Its Legacy*

Once one understands that the request for tissue donations is simply a species of charitable solicitation, any effort to regulate such solicitation must take into account the law governing the free speech rights of charities. As Professor Leslie Espinoza documented in her article, *Straining the Quality of Mercy: Abandoning the Quest for Informed Giving*, charities first incorporated and began to employ vigorous fundraising practices in the mid-twentieth century.<sup>78</sup> The status of charities as corporations, rather than trusts, led to complicated struggles over the regulation of these entities, in particular over the extent to which states could exercise oversight by reviewing things such as a charity's investments or compensation.<sup>79</sup> By the end of the 1950s, the public outcry against charities' in-person and telephone solicitation tactics curtailed this debate and led state and local governments to articulate regulations aimed at monitoring solicitors.<sup>80</sup>

One of the most common ways in which state and local governments have sought to regulate solicitors is to target for-profit entities that solicit on behalf of nonprofit charities, retaining a large portion of the revenues they raise for their own corporations.<sup>81</sup> This particular practice is a popular target of lawmakers in part because of the concern that donors may mistakenly believe that their donations will enrich only the charity, rather than being used in some (often large) part to generate revenue for a private corporation working on behalf of their charity.<sup>82</sup> These regulations are relevant to solicitations made directly by nonprofit charities (including OPOs) in that they raise the issue of the extent to which the government can compel solicitors to make specific disclosures when approaching prospective donors.

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78. Leslie G. Espinoza, *Straining the Quality of Mercy: Abandoning the Quest for Informed Charitable Giving*, 64 S. CAL. L. REV. 605, 643 (1991).

79. *Id.* at 642-43.

80. *Id.* at 643.

81. *See id.*

82. The political coalition supporting the targeting of for-profit "professional" fundraisers is quite interesting. As Espinoza notes, these regulations were supported by established U.S. charities seeking to eliminate competition from smaller charities that lacked the resources to raise funds on their own. *See id.*

In a series of cases dating back to 1980, the U.S. Supreme Court has carefully delimited the extent to which state and local governments can compel disclosures by those who solicit on behalf of charitable entities. Specifically, beginning with *Village of Schaumburg v. Citizens for a Better Environment*, the Court has rejected laws that sought to preclude solicitation by those retaining more than a specific percentage of revenues.<sup>83</sup> In later cases, the Court rejected a more flexible statute that permitted solicitation by fundraisers retaining more than twenty-five percent of revenues if the charity could prove that such limitation would, in effect, prevent it from raising funds.<sup>84</sup> Finally, the Court rejected a statute designed to protect the public from fraud by requiring, among other things, that those soliciting disclose their fundraising costs at the time of their solicitation.<sup>85</sup> In all three of these cases, which are often referred to as the “trilogy,”<sup>86</sup> the Court opined that the speech of the solicitors was not purely commercial and therefore was entitled to First Amendment protection.<sup>87</sup>

In 2003, the Court decided the case of *Madigan v. Telemarketing Associates*, which addressed whether the law offers any protection to naïve donors.<sup>88</sup> *Madigan* involved a claim by the Illinois Attorney General that solicitors on behalf of VietNow, a charity that benefits veterans, fraudulently misled donors by asserting that “a significant amount” of each dollar went to services for veterans when, in fact, fifteen cents or less of each dollar was received by VietNow, and of which, only three cents would be used for services.<sup>89</sup> In its defense, the charity contended that “the statements made by [Telemarketers] . . . are alleged to be ‘false’ only because [Telemarketers] retained

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83. *Vill. of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620 (1980) (declaring unconstitutional an ordinance that conditioned the grant of solicitation permits upon proof that the charitable organization used at least seventy-five percent of the money).

84. *Sec'y of State v. Joseph H. Munson Co.*, 467 U.S. 947 (1984) (declaring that significant fundraising activity is protected by the First Amendment and holding that the percentage limitation in the state statute was unconstitutionally overbroad).

85. *Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781 (1988) (finding unconstitutional for failure to narrowly tailor a state law prohibiting professional fundraisers from retaining an “unreasonable” or “excessive” fee). The Court did note in dicta that a state might require a solicitor to disclose his or her “professional status” as an employee of a company making solicitations on behalf of a charity. *Id.* at 799 n.11. It is not at all clear that members of the public would understand this to mean that only a small percentage of their contribution will reach the charity. Thus, unless the prospective donor asks what percentage of the donation will go to the charity, this information need not be revealed.

86. *Illinois ex rel. Madigan v. Telemarketing Assocs. Inc.*, 538 U.S. 600, 614 (2003).

87. *See Citizens for a Better Environment*, 444 U.S. at 632; *see also Riley*, 487 U.S. at 788; *Joseph H. Munson Co.*, 467 U.S. at 960.

88. *Telemarketing Associates*, 538 U.S. 600.

89. *Id.* at 607 n.1.

85% of the gross receipts and failed to disclose this information to donors.”<sup>90</sup> Thus, they claimed that the state was attempting to regulate them based upon a percentage-rate limitation, which is impermissible under the trilogy.<sup>91</sup> The Court rejected that position and held that “[s]o long as the emphasis is on what the fundraisers misleadingly convey, and not on percentage limitations on solicitors’ fees *per se*, such actions need not impermissibly chill protected speech.”<sup>92</sup> Thus, it is clear that charitable solicitations must be made in accord with state laws against fraud.

The practical result of this framework for regulating charitable solicitations is that donors are protected only insofar as the state can prove that a solicitor’s actions amounted to misrepresentation.<sup>93</sup> In so doing, the Court has endorsed what Professor Espinoza termed “a new form of *caveat emptor*.”<sup>94</sup> Under the “giver beware” model, donors are expected to be sophisticated benefactors, scrutinizing any available information, such as the Internal Revenue Service’s public records of an institution’s financial status, prior to making a contribution.<sup>95</sup> As Kent Wittrock suggested in his Note on the *Madigan* case, “[I]t is unrealistic to expect donors to seek out financial information and make donation decisions according to this information. Equally unrealistic is the suggestion that a donor protect him or herself through self-education when it is the donor’s very generosity that permits continuous solicitation.”<sup>96</sup> The burden on donors becomes particularly acute when one considers the context in which OPO agents solicit donations of human tissue.

### 3. *Striking the First Amendment Balance in the Context of Tissue Solicitation*

Seen in the context of the law’s resistance to requiring solicitors to disclose their revenue sharing arrangements, the proposed federal regulations governing the solicitation of human tissue are relatively rigorous. Solicitors must disclose all possible uses of the tissue, as well as

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90. *Id.* at 610 (citing the Illinois Supreme Court’s decision in *Ryan v. Telemarketing Associates, Inc.*, 763 N.E.2d 289, 297 (Ill. 2002)) (alterations in original) (internal quotation marks omitted).

91. *See id.*

92. *Id.* at 619.

93. *See id.* at 613 (explaining that the state’s legitimate interest in preventing misrepresentation is better served by the use of the penal laws than by prohibiting solicitation generally).

94. Espinoza, *supra* note 78, at 669.

95. *Id.*

96. Kent D. Wittrock, Note, *The End of Fraudulent Solicitation—Really?: The Supreme Court in Madigan v. Telemarketing Associates Provides That Fraudulent Statements in Charitable Solicitation Are Not Protected Speech*, 72 UMKC L. REV. 275, 287–88 (2003) (internal citations omitted).

the fact that recipients may include for-profit entities.<sup>97</sup> They must further inform donors of their right to restrict their donations so that certain uses or certain recipients may be set off-limits.<sup>98</sup> It remains to be seen whether representatives of the tissue industry will challenge these regulations as too restrictive of their First Amendment rights. Certainly, the for-profit sector of this industry has much to fear from mandatory disclosure. At the very least, it seems likely that full disclosure will constrict the supply of available tissue. Moreover, as I discuss below, the ability of the for-profit tissue industry to enhance its access to tissue may be limited, as the solution of offering to pay donors for tissue is impermissible under current laws.<sup>99</sup> Thus, the chilling effect that these regulations likely will have on the willingness to donate may lead to challenges against these regulations.

Toward that end, it is useful to explore the extent to which these regulations are able to withstand scrutiny under the First Amendment. In this section, I will consider only the extent to which the substance of the proposed regulations is unduly burdensome in its scope. I demonstrate that contemporary jurisprudence not only supports the scope of the present regulations, but indeed would seem to demand a more extensive disclosure than presently proposed. In this subsection, I will discuss the extent to which a more rigorous disclosure is likely to accomplish the goals of protecting the public from fraud, as well as the practical implications of a more thorough disclosure on the tissue industry and tissue transplantation practices as a whole.

Those engaged in the retrieval and processing of human tissue might object to the government's proposed regulations by arguing that they impermissibly limit free speech rights. The Supreme Court has recently held that even when for-profit agents are soliciting on behalf of a nonprofit charity, their speech is only partially commercial in nature and is therefore protected under the doctrine of free speech.<sup>100</sup> The Court has found that the educational or advocacy mission of the solicitor triggers this protection, and as such, the government's desire to protect the public from fraud is not sufficient in and of itself to permit it to impose disclosure requirements upon solicitors.<sup>101</sup> In-

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97. See Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations, 70 Fed. Reg. 6086, 6119 (proposed Feb. 4, 2005) (to be codified at 42 C.F.R. pt. 486.342).

98. *Id.*

99. See 42 U.S.C. § 274e (2000) (prohibiting the sale of "kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof").

100. See *Illinois ex rel. Madigan v. Telemarketing Assocs. Inc.*, 538 U.S. 600 (2003).

101. *Riley v. Nat'l Fed'n of Blind*, 487 U.S. 781, 801 (1988) (asserting that the state's power to constrain fundraisers must be weighed against First Amendment rights).

stead, the goal of protection from fraud must be balanced against the charities' First Amendment rights.<sup>102</sup> Thus, the regulations must be narrowly tailored to the state interest in preventing fraud and must not be unduly burdensome on the charities' right to free speech.<sup>103</sup>

In the case of the solicitation of human tissue, it is clear that the purpose behind the new regulations is to uphold the government's interest in protecting the families from fraud. The open question is whether the mandatory disclosure rules are an unduly burdensome means of protecting the public from fraud. The industry might readily argue that these regulations are indeed unduly burdensome on its free speech rights. As drafted, the proposed tissue regulations' disclosure provisions are significantly more detailed than those state and local regulations previously ruled unconstitutional by the Court. Moreover, to the extent that the mandatory disclosures are time-consuming and result in a decreased supply of tissue, the industry might argue that the regulations have a negative impact upon a charity's ability to perform its mission.<sup>104</sup> Even a cursory review of this argument reveals it to be implausible. It seems absurd to argue that disclosure should not be required because, when it is, donors revise their preferences. The very fact that donors behave differently would attest to the materiality of the information disclosed. The proposed regulations therefore might be defended on the grounds that they are consistent with state common law governing fraud. This defense did not work in the trilogy cases because there was little or no evidence linking the high fundraising costs of professional solicitors to a higher likelihood of fraud.<sup>105</sup> Thus, the Court found that banning solicitation by those with high fundraising costs, or even mandating disclosure of those costs, would not necessarily diminish fraud.<sup>106</sup> Instead, by inviting the public to make the inference that high costs equate to fraud, the regulations impermissibly prejudiced the public against charities that used the services of professional fundraisers.

In the case of tissue solicitation, by contrast, nondisclosure, or even partial disclosure, is almost certain to mislead prospective donors.

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102. *Id.*

103. *See id.* at 800.

104. One study done in New Jersey revealed that thirty-three percent of those surveyed believe that the use of donated tissue "should be restricted to treatment of disease and injury." *See* Eagleton Inst. of Pol., Ctr. for Pub. Interest Polling, *New Jerseyans' Opinions on Organ and Tissue Donation*, at 7 (Feb. 2001).

105. *See, e.g.,* *Sec'y of State v. Joseph H. Munson Co.*, 467 U.S. 947, 966 (1984) (holding that there is no nexus between the percentage of funds retained by the fundraiser and the likelihood that the solicitation is fraudulent).

106. *Id.* at 967.

Recall that the risks of fraud in this context include nondisclosure of the potentially offensive end uses of the tissue and a failure to note the extent to which the donation works to enhance the wealth of a for-profit enterprise. By mandating the disclosure of information pertaining to the possible uses and users of donated human tissue, the law enlightens donors, enabling them to make more informed choices about whether and how to donate.

Ironically, the more compelling argument for the tissue industry is that the disclosures mandated by the proposed regulations do not go far enough, and therefore are equally likely to generate prejudice as are disclosures pertaining to high fundraising costs. For instance, merely disclosing that donated tissue might be sold to a for-profit company fails to convey the fact that these for-profit industries create products that are vital to many medically necessary and compelling treatments.<sup>107</sup> Thus, without an extremely lengthy explanation by the soliciting agent, a bald statement that some tissue might go to for-profit entities risks generating a distorted image of the range of uses of donated tissue.<sup>108</sup>

Therefore, one might argue that the proposed regulations require too little disclosure, and that the only way to protect the public from fraud, while simultaneously guarding against the risk of prejudicial inferences being drawn from the disclosure of information pertaining to the end uses and users of donated tissue, is to require an even more thorough disclosure than is presently mandated by federal regulations. This disclosure would include a discussion of the range of for-profit entities who work with human tissue, the variety of ways in which they might use or distribute this tissue, and the nature of the treatments for which such tissue routinely is used.

Mandating such a thorough disclosure would be unprecedented in the context of charitable solicitations, and it clearly escalates the impingement upon the First Amendment rights of the soliciting agency. It is not, however, radical. Indeed, even a brief review of the law governing fraud and misrepresentation reveals that solicitors owe potential donors nothing less. Support for a more rigorous disclosure may

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107. For example, CryoLife Inc. is a for-profit company making sixty million dollars per year predominately by freezing heart valves for later use in life-saving surgeries. See *Tissue Supply, Demand Make for Odd Alliances*, ORANGE COUNTY REG., Apr. 16, 2000, available at [http://www.ocregister.com/features/body/day1\\_who.shtml](http://www.ocregister.com/features/body/day1_who.shtml). See also Heisel et al., *supra* note 43 (discussing the life-saving uses for Alloderm such as filling holes made by tumors, providing slings for weak bladders, and providing new skin to burn victims).

108. The negative implications for the for-profit industry are particularly troubling in light of the nebulous distinction between the for-profit and the nonprofit sectors of the tissue market. See *supra* Part II.B.

be found in the law of securities, wherein the half-truth rule treats as an affirmative misrepresentation a statement in which a “partial disclosure of facts [is] literally correct but misleading in light of facts that are concealed . . . .”<sup>109</sup>

More generally, support also is found in the common law governing misrepresentation. Consider, for example, § 161 of the *Second Restatement of Contracts*:

A person’s non-disclosure of a fact known to him is equivalent to an assertion that the fact does not exist in the following cases only:

- (a) where he knows that disclosure of the fact is necessary to prevent some previous assertion from being a misrepresentation or from being fraudulent or material,
- (b) where he knows that disclosure of the fact would correct a mistake of the other party as to a basic assumption on which that party is making the contract . . . .<sup>110</sup>

As already noted, those who solicit tissue donations are not acting as fiduciaries, protecting the interests of those asked to donate.<sup>111</sup> Nor are the solicitors acting altruistically. Instead, they seek to induce the donors to enter into a transaction that will be altruistic on *the donors’* part. This is a classic arm’s length transaction. To the extent that solicitors of human tissue remain silent about the full range of uses to which a tissue donation may be put, they are misrepresenting material facts. As a result, their silence arguably precludes the formation of a contract.<sup>112</sup> The “contracts” they procure by virtue of their silence should be voidable, if not completely void.

As such, although it is unprecedented in the context of charitable solicitations, requiring a comprehensive disclosure is not legally problematic; indeed, it is legally mandated. Instead, the problem with such a proposal is practical in nature. Even if one imagines the most sensitive of agents, it is painful to imagine the process by which he or she will lead the recently bereaved family through a rigorous disclosure.

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109. See Dale Arthur Oesterle, *The Inexorable March Toward a Continuous Disclosure Requirement for Publicly Traded Corporations: “Are We There Yet?”* 20 CARDOZO L. REV. 135, 143–44 (1998).

110. RESTATEMENT (SECOND) OF CONTRACTS § 161 (1981).

111. See *supra* notes 75–80 and accompanying text.

112. See RESTATEMENT (SECOND) OF CONTRACTS §§ 163–64 (1981). This assumes that the misrepresentation pertains to the essential terms of the proposed contract and that the donor lacked reasonable opportunity to verify the accuracy of those terms. Plainly, information pertaining to the end uses of one’s gift is an essential term of the proposed contract and, given the delicate nature of the timing of such solicitations, it is unreasonable to expect donors to investigate such end uses on their own. Even if a court finds that the contract is not void, it should find these agreements voidable at the insistence of a donor who can show that the agreement was induced by the solicitor’s misrepresentation.



It is this consideration that frames my broader set of concerns with the proposed regulations.

## V. THOROUGH DISCLOSURE'S POTENTIAL DOWNSIDES

Although I have argued that the law supports mandating a robust disclosure when soliciting tissue from families of the deceased, it is my belief that this solution will not fully remedy the risk that families will be misled, and more importantly, is likely to give rise to a host of problematic consequences. In this section, I will discuss three such consequences: undermining public trust in transplantation, constricting the supply of tissue available for transplantation, and exacerbating legal problems regarding the timing and nature of tissue solicitation. I will conclude that not only is disclosure not enough to protect the public from fraud, but insofar as it is offered in isolation, it poses a significant threat to the viability of the tissue transplantation industry, and perhaps even to the broader organ transplantation as well.

### A. *Thorough Disclosure's Potential Threat to Organ and Tissue Solicitation*

For years, the tissue procurement industry has resisted pressure to mandate more thorough disclosure to families during the solicitation process, claiming that such disclosure might have a negative impact upon the family's willingness to donate.<sup>113</sup> Although this justification for resisting disclosure has been offered without elaboration and is rather easy to reject, it is nonetheless important to explore, if only briefly, the potential threat that full disclosure might pose to the organ and tissue procurement industry as a whole in the absence of any other incentives to donate.

In essence, the threat raised by a thorough disclosure is as follows. The agent seeking the donation would be forced to tell the donor family that the tissue from their loved one's body could be used by a host of different intermediaries, who would render it useful to people with maladies ranging from burns to heart disease to bone loss to small penises to thin lips. Upon hearing this, in addition to feeling overwhelmed by the amount of information they have been asked to absorb, the families might start to feel somewhat uncomfortable about giving away parts of their loved ones' bodies.<sup>114</sup> On one hand, it might be nice to help those in need. On the other hand, there are so many players in this industry, all standing to benefit (if not to profit)

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113. See *supra* note 62 and accompanying text.

114. See *supra* note 104.

by using the tissue they donate. Even if the families do not start feeling resentful about being asked to make a gift to this industry, they might be a bit repulsed by the realization that the solicitor is not there to comfort them, but rather to gain access to their loved ones' bodies.

There is an extensive literature considering the problem of organ shortages in this country. Most authors seem to blame the shortage on the distrust of doctors, and indeed of the healthcare system in general, that is felt in particular by certain already subordinated sectors of the population.<sup>115</sup> It seems that there is a strong association between lack of access to the healthcare system and refusal to donate organs.<sup>116</sup> Some suspect that this association reflects the concerns of minority populations, such as African Americans, that their organs will not be used to benefit other African Americans.<sup>117</sup> Others suggest that the problem is more general—those who have been excluded from the healthcare system for most or all of their lives may have little reason to want to support that system upon their deaths.<sup>118</sup> Either way, a solicitation for a donation that includes detailed information about the end uses of human tissue by for-profit agencies seems likely to add fuel to this particular fire.

A thorough disclosure regarding the potential uses and users of donated tissue may intensify the distrust felt by some toward the entire organ and tissue transplantation enterprise. Those who are confused or alarmed when approached—within hours of losing their loved one with a request that they donate the body to this complicated industry—might understandably refuse altogether, rather than taking the time to identify which parts they are inclined to give and to whom. Thus, a rigorous disclosure surrounding tissue transplantation might play into the pre-existing problem of distrust, thereby further constricting not only the nation's supply of human tissue, but also to its supply of solid organs. Moreover, the most obvious way to combat this risk is to provide an even more thorough explanation to the prospective donors about the differences between the organ and the tissue transplant industries. Given the timing of these solicitations, however, this course of action may be impractical.<sup>119</sup> Moreover, it is

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115. See Goodwin, *supra* note 5, at 312.

116. *Id.* (stating that “African Americans demonstrate a diminished or guarded willingness to participate in the present altruistic system”).

117. *Id.* (“Their [African Americans] concerns are well-documented in the literature: mistrust of the medical profession, and doubts that their organs will be used to benefit other African Americans.”).

118. *Id.*

119. Of course, it is possible for a donor to consent to the donation of an organ while refusing to donate tissue. Indeed, at least some OPOs already use separate consent forms or separate

likely to make the tissue industry look not just different, but bad by comparison. This leads to my third concern with the disclosure solution.

### *B. Disclosure's Potential Impact on Tissue Supply*

The disclosure regulations presuppose that donors are interested in knowing whether the recipients are nonprofit organizations, as opposed to for-profit corporations. Indeed, presumably donors will be more than merely interested in knowing this information—one assumes that they will be less likely to give away their loved ones' tissue to those who will be using it to make a profit.<sup>120</sup> This would seem to be highly rational on their part, as one of the basic laws of transactions between humans is that “you cannot get something for nothing.”<sup>121</sup> If the for-profit companies are getting “something” from the families (and, of course, all available information suggests that they are), then the rational donor will no longer perceive himself or herself as a benefactor, but rather as a chump.

This sentiment portends trouble for the for-profit sector of the human tissue industry. Even though the line between nonprofit and for-profit entities involved in the human tissue industry is nebulous at best,<sup>122</sup> the implication of this disclosure to patients is that the nonprofits are charitable (read “deserving”) entities, whereas the for-profits simply exist to enrich their shareholders. If donor families behave “rationally,” then as mandatory disclosure guidelines are imple-

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sections on a single consent form to distinguish the two types of donations. See, e.g., Louisiana's Consent for Anatomical Gift, <http://www.lopa.org/forms/2005%20Consent%20Form-1.pdf> (last visited Sept. 30, 2005). These forms, however, do not provide, nor can they readily accommodate, the thorough disclosure about the end-uses of tissue donations urged by this analysis.

120. See *supra* note 104 and accompanying text. Another recent survey of tissue donor families conducted by the National Donor Family Council and Case Western Reserve University indicated that families “would have preferred receiving more, rather than less, information to aid them in their decision making. . . . 79 percent of families surveyed said that they would have wanted to know that some tissue banks are for-profit . . . .” 70 Fed. Reg. 6111, 6111.

121. See Henry Winthrop Ballantine, *Mutuality and Consideration*, 28 HARV. L. REV. 121, 121 (1914). Ballantine wrote:

From a nude pact no obligation arises. The courts have not felt impelled to extend a remedy to one who seeks to get something for nothing. English law accordingly will not usually enforce a promise unless it is given for value, or the promise of value, *i.e.*, something which the law must assume to be of some value to the promisor and which the parties make the subject of bargain or exchange.

*Id.*

See also RESTATEMENT (SECOND) OF CONTRACTS § 71 (1981) (“To constitute consideration, a performance or a return promise must be bargained for. . . . A performance or return promise is bargained for if it is sought by the promisor in exchange for his promise and is given by the promisee in exchange for that promise.”).

122. See Katz, *supra* note 11, at 961–62.

mented, one would expect the supply of tissue available to for-profit corporations to constrict rather dramatically.<sup>123</sup> Moreover, current federal law severely restricts the options available to the industry in responding to a diminished supply of human tissue. In this section, I will discuss the legal barriers to remedying this threat.

### 1. *NOTA and the Ban on Paying for Human Tissue*

The biggest problem facing the for-profit tissue industry in the event of a constricted supply of human tissue is that the most obvious way to increase supply is presently illegal. The National Organ Transplant Act of 1984 (NOTA) prohibits the payment of valuable consideration to any person in exchange for organs or tissue.<sup>124</sup> NOTA does, however, permit compensation for the “reasonable” costs incurred by those who retrieve organs and tissue.<sup>125</sup> As a result of the law’s ambiguity in this regard, those involved in the retrieval and processing of human tissue are permitted to recover what one expert calls “supernormal profits” all in the name of covering their costs.<sup>126</sup> In fact, some question the extent to which “costs-based” compensation is actually somewhat of a cover for a symbiotic, or even a subversive, relationship between the for-profit and the nonprofit sectors of this industry.<sup>127</sup>

In virtually all cases, the donor family is not compensated, but instead is expected to make a gift of its loved one’s tissue.<sup>128</sup> This law often is touted as reflecting a belief that human organs and tissue belong with the sacred class of things deemed too valuable, and perhaps too dangerous, to be treated as commodities.<sup>129</sup> Of course, the reality is that the market in human tissue is quite vibrant. The market for

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123. Of course, some may continue to donate tissue for use by for-profit entities, recognizing the benefit generated by the products they produce.

124. National Organ Transplant Act (NOTA), 42 U.S.C. § 274e(a) (2000).

125. *Id.* § 274e(c)(2) (“[T]he term ‘valuable consideration’ does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ . . .”).

126. See Katz, *supra* note 11, at 947 (defining supernormal profits).

127. See Katches et al., *supra* note 2. See generally Katz, *supra* note 11 (discussing the difficulty of reconciling NOTA’s “reasonable” payment requirement with the current tissue industry’s system of interrelated nonprofit and for-profit tissue agencies, culminating in the for-profit tissue processors reaping supernormal profits from the sale of their patented tissue products).

128. Telephone Interview with Thomas Mone, *supra* note 27. Mone notes that on very rare occasions, a family will respond to a solicitation by stating that they are quite poor and lack even the funds needed to bury their loved one. In some of these cases, the OPO will offer, in exchange for the donation of the tissue or organs of the deceased, to make a donation to a local church in order to cover funeral expenses. *Id.*

129. See Mahoney, *supra* note 54, at 173 (acknowledging and discussing some of the dangers and concerns of placing a value on human body parts).

human tissue simply excludes payment to the sources, so that the long series of bargained-for exchanges that mark this industry begins after the initial donation rather than with a purchase of raw materials.

Others have written extensively about the debate over whether to compensate the donors of human tissue or their survivors.<sup>130</sup> In perhaps the most powerful critique of those who oppose such compensation, Professor Julia Mahoney noted that the system we presently have is not at all gratuitous, but rather permits compensation—and indeed profit—at every stage of utilization of donated tissue. Thus, she concluded:

[T]he eradication of commerce in human biological materials would require the *total* abandonment of the price system as a vehicle for allocating rights to human components. In place of the price system, rights associated with human biological materials would have to be gratuitously transferred at every stage of distribution, with the forces of generosity (or a governmental entity) guiding tissue from its original human source to its ultimate consumer.<sup>131</sup>

Regardless of whether one accepts the argument that a market in human tissue already exists or that it should be tolerated, if not embraced, by those who support the development of research and technologies utilizing human tissue, it is imperative to note that the new regulations may render the debate moot. Instead, it seems that the likely impact of the disclosure regulations will be to force consideration of a human tissue market. If a substantial portion of families respond to disclosure by refusing to donate their loved ones' tissue to those who intend to use it to make money, and if the for-profit entities are barred from offering to compensate families, then these entities will lose access to the raw material that they need in order to survive. The companies will be forced either to restructure as nonprofit entities or to sell their patents and close their doors.<sup>132</sup>

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130. See Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257 (2004). See also Charlotte H. Harrison, *Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77 (2002).

131. Mahoney, *supra* note 54, at 197.

132. Another factor relevant to tissue supply is the issue of stem cells, which hold the potential to revolutionize healthcare in various areas, including the manufacture of various tissues. If stem cells perform as hoped, the entire field of tissue transplantation might be transformed so as to eliminate the need for donations. For instance, in the future, stem cells might be used to develop specific tissues, such as skin, corneas, and bone, and the processing companies will become distributors for the biotech firms that manufacture these tissues. Telephone Interview with Joel Frader, Div. Head, Gen. Pediatrics, Children's Mem'l Hosp., Chicago, Ill. (Sept. 2, 2005).

## 2. *The Problems Created by Paying for Human Tissue*

Even if NOTA were amended to permit families to be compensated for permitting OPOs to recover their loved ones' tissue, this practice would trigger several complicated and related problems. First, an offer to pay families for permitting the retrieval of their loved ones' tissue would trigger the broader controversy associated with treating body parts as market commodities, specifically the concern that such commodification might be both degrading and potentially coercive.<sup>133</sup> Second, there is the practical problem of the effect of offering compensation for tissue on the ability of the nonprofit sector to encourage altruistic donations of tissue and organs. In this subsection, I will discuss the pricing problem, reserving discussion of the logistical problems for the subsection that follows.

The problem of treating human tissue as a commodity was first raised by the landmark case of *Moore v. The Regents of the University of California*.<sup>134</sup> In that case, researchers took cells from John Moore, a leukemia patient, and used them to develop a cell line that had numerous commercial applications. When Moore learned of this "theft," he sued the doctors and researchers for a range of civil harms, including not only their failure to obtain informed consent, but also conversion. The California Supreme Court agreed that Moore had a legitimate complaint for negligence due to the doctors' apparent failure to disclose their conflicts of interest.<sup>135</sup>

The court declined, however, to recognize Moore's claim for conversion, finding that no case to date had recognized a property right in human cells and worrying that doing so would "impose a tort duty on scientists . . . [This duty] would affect medical research of importance to all of society, implicat[ing] policy concerns far removed from

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133. Of course, the claim that it is inherently offensive or impossible to set a price on human body parts is spurious, as the industry already prices all sorts of human tissue once it is out of the control of the donor's family. Likewise, the claim that there is too much harm inherent in offering compensation in exchange for organs has largely been refuted by the work of scholars such as Michele Goodwin. See, e.g., Goodwin, *supra* note 5. Even if one is inclined to favor a ban on the sale of human organs on the grounds that such offers would prove to be coercive and corrosive of human dignity, see, e.g., Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849 (1987), this argument need not apply with equal force to the sale of human tissues taken from the deceased. In the case of the latter, there is no real threat of coercion, and other than arguments predicated upon the need to guard against the proverbial slippery slope, it is hard to see why the offer of a small amount of compensation for human tissue undermines the dignity of our species.

134. *Moore v. Regents of the Univ. of California*, 793 P.2d 479 (Cal. 1990) (holding that the plaintiff did not retain ownership interest in cells after they left his body and thus could not assert conversion claim).

135. *Id.* at 484 (stating that "a physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties").

the traditional, two-party ownership disputes in which the law of conversion arose.”<sup>136</sup> The court acknowledged that Moore had been harmed, but they viewed the harm as dignitary in nature. In short, he should have had the right to refuse to give his tissue away. The court rejected Moore’s claim that he was owed money by those who had profited by taking his cells and using them to make a patented cell line, stating: “[T]he theory of liability that Moore urges us to endorse threatens to destroy the economic incentive to conduct important medical research. If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery.”<sup>137</sup>

Clearly, the *Moore* court overstated its concern when it opined that the natural outcome of recognizing Moore’s property interest in his own cells would be to destroy the incentive to conduct scientific research.<sup>138</sup> One might readily identify ways to compensate Moore for the unauthorized taking of his cells without impeding the researchers’ capacity to reap a large profit. Indeed, this possibility is built into the “disclosure” solution articulated by the *Moore* court.<sup>139</sup>

Researchers or organ procurement agents might seek permission from a patient or his or her survivors to extract cells or tissue. Once these solicitors disclose their personal motives, however, the prospective donors might refuse unless they receive some form of compensation. Nor is there reason to assume that the compensation should be limited to a share in the profits that might ultimately be derived from the tissue. Instead, the researchers or agents might offer a flat payment for the raw material that the patient provides to them. This is, after all, in keeping with the way in which virtually every other for-profit industry operates. One might seek to enlarge one’s profit margin by paying the least amount possible for raw materials, but certainly a company has no reason to expect that raw materials should be given to it free of charge.

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136. *Id.* at 487.

137. *Id.* at 495–96.

138. *Id.* at 487.

139. Incidentally, this result is anticipated by the *Brotherton* case, in which the court permitted a surviving spouse to sue, on due process grounds, for the wrongful taking of her deceased husband’s corneas. See *Brotherton v. Cleveland*, 923 F.2d 477 (6th Cir. 1991). One might assume that the court’s holding—“the removal of Steven Brotherton’s corneas were caused by established state procedures and that Ohio failed to provide the necessary predeprivation process”—anticipates a monetary remedy for the wrongful taking. *Id.* at 482.

### 3. *Logistical Problems Generated by a Market Solution*

Assuming that principled objections to paying for human tissue are resolved and that the law comes to permit payment of some sort in exchange for human tissue, there remain a host of logistical problems. Ironically, these practical concerns may prove to be at least as tenacious as the problem of compensation itself.

One problem triggered by permitting payment for human tissue is the issue of whether payment would then have to be offered for all human tissue, and perhaps also for organs.<sup>140</sup> At first blush, it might seem that the commercial market in human tissue could coexist with the altruistic market. The tissue industry might offer prospective donors of tissue, whether patients or their surviving families, the opportunity to donate to a charitable cause or to sell their tissue to a commercial venture.

What complicates the prospect of permitting the altruistic market to coexist with a commercial market in human tissue is the fact that, as of today, the nonprofit industry does all of the soliciting and recovery of tissue.<sup>141</sup> Thus, one assumes that the agents for the nonprofit industry would have both the task of soliciting donations of tissue and organs for nonprofit uses and also the task of offering compensation for tissue on behalf of for-profit corporations. This relegates to the OPO agents a task rife with conflicts of interest, as one assumes that agents' primary allegiance will be to their employers, which will require tissue donations in order to maintain their enterprises. At the same time, it may be too much to expect altruism from family members who would be asked to choose between making a gift of tissue or being paid for it. The direct juxtaposition of these options may spell the demise of the altruistic system of organ and tissue donations. Furthermore, the most readily apparent solution to this problem—to encourage the for-profit industry to engage agents to solicit on its own behalf (a practice that would be legal under current law)—raises the disturbing scenario of multiple bedside solicitations.

Indeed, it is the timing of tissue solicitations, even if not accompanied by an offer of money, that triggers the third concern I raise in arguing that disclosure is not enough to resolve the problems inherent in tissue solicitation.

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140. It is worth noting that the current shortage of transplantable organs may mean that payment for "donations" is inevitable. See, e.g., Gretchen Reynolds, *Will Any Organ Do?*, N.Y. TIMES, July 10, 2005, (Magazine), § 6, at 37 (describing the use of "marginal" organs due to the shortage of healthy transplantable organs). Several states offer tax incentives to families who agree to donate the organs of a deceased family member. *Id.*

141. See Katz, *supra* note 11, at 955.



### C. Legal Concerns Regarding the Process of Solicitating Tissue

It is hard to imagine a less auspicious moment for negotiating a transaction than the first twenty-four hours after the death of a loved one. This time frame, so far removed from the state of mind one associates with an ideal arm's length transaction, or even with a charitable donation, is precisely the time during which families are asked to donate their loved ones' tissue. The family's vulnerability raises troubling legal problems in the event that the law permits payment for tissue. Indeed, some of these legal concerns are present even if payment remains illegal.

#### 1. The Law of Unconscionability and the Purchasing of Human Tissue

In considering the scenario of solicitations for tissue, one cannot help but call to mind the leading case on unconscionability, *Williams v. Walker-Thomas Furniture Co.*<sup>142</sup> That case embraced the doctrine of "unconscionability" in describing deals marked by "an absence of meaningful choice on the part of one of the parties together with contract terms which are unreasonably favorable to the other party."<sup>143</sup> Commentators have noted discomfort with the fact that the company used door-to-door salesmen, whose contracts contained complicated, one-sided legal terms and who approached their impoverished "buyers" on the day the buyers received their monthly support allowance from the government.<sup>144</sup>

In the case of tissue solicitation, these same concerns are present, and perhaps even heightened. There is the bedside or in-home solicitation of grieving family members, who do not seek out an opportunity to make a deal, and may not even know that they are being asked to negotiate. Add to this the imbalance of information, the time-pressured nature of the decision families are asked to make, and the fact that they are not in a position to investigate the meaning or validity of the OPO agent's disclosure of the possible end uses of the tissue, and it is hard to imagine that the resulting deals would withstand legal scrutiny.

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142. *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445 (D.C. Cir. 1965).

143. *Id.* at 449.

144. See Eben Colby, Note, *What Did the Doctrine of Unconscionability Do to the Walker-Thomas Furniture Company?*, 34 CONN. L. REV. 625, 649 (2002) ("The furniture company employed salesman that went door-to-door and worked on commission. As such, there is little doubt that many of the sales made by the furniture company were the result of high-pressure sales tactics that pushed items that customers really did not need.").

This latter concern about the fairness of the solicitation process is properly viewed as a subset of the larger set of considerations regarding the timing and nature of the solicitation of human tissue. As these concerns exist regardless of whether families are offered compensation or simply are being asked to donate tissue, I will discuss them together in the following subsection.

## 2. *Ambulance Chasing, One-Sided Bargains, and the Bedside Solicitation for Tissue*

Setting aside the controversial issue of offering compensation for tissue, one still must consider whether disclosure fully protects the family from overreaching, given the sensitive nature of the timing of the solicitation of donations of human tissue. To the extent that they are behaving in an economically rational manner, one would expect that most families would refuse to make gifts to the for-profit tissue industry. After all, no matter how laudable the cause, corporate America typically does not solicit individual members of the public for donations. When the public's help is needed, individuals are offered incentives to enter into contracts with businesses.<sup>145</sup> Items are offered for sale at reduced prices. In extreme cases, an industry might seek the government's assistance in sustaining it through a particularly difficult economic period.<sup>146</sup> But it strains credulity to imagine United Airlines or Ford Motor Company asking the general public for donations to help support its corporate mission.

One must therefore think seriously about whether and why this industry might succeed in obtaining donations from individuals, even after fully informing them about the profits that will be generated as a result of their donations. In other contexts, the law recognizes the vulnerability associated with death or other such trauma and attempts to shield the bereaved individuals from those who might prey upon them. Perhaps the best illustration of this practice is seen in the laws governing the solicitation of clients by attorneys in the aftermath of death or accident. Popularly known as "ambulance chasing," states long have attempted to limit the rights of attorneys to solicit business

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145. American car manufacturers, for instance, may offer incentives such as zero percent financing or a certain amount of money to be returned to the customer upon purchase of a new car (cash-back). See, e.g., Financing Options, <http://www.safecarguide.com/gui/fin/financing.htm> (last visited Mar. 28, 2006).

146. For instance, consider the use of bankruptcy laws to permit United Airlines to remain in business. See Micheline Maynard, *2 Major Airlines Seen Near Bankruptcy Filings*, N.Y. TIMES, Sept. 14, 2005, at A1 (discussing the possibility of Delta and Northwest Airlines joining United Airlines by filing for bankruptcy in order continue operating while reorganizing under court protection).

from the newly bereaved.<sup>147</sup> Although lawyers' rights to advertise are protected under the First Amendment,<sup>148</sup> the law long has limited the scope of that right when the context for solicitation includes "any . . . situation that breeds undue influence—by attorneys or their agents . . . ."<sup>149</sup> The Court has singled out for particular scrutiny the practice of in-person solicitation, finding that a state may regulate against it without having to prove any actual injury:

Unlike . . . advertising . . . , in-person solicitation is not visible or otherwise open to public scrutiny. Often there is no witness other than the lawyer and the lay person whom he has solicited, rendering it difficult or impossible to obtain reliable proof of what actually took place. This would be especially true if the lay person were so distressed at the time of the solicitation that he could not recall specific details at a later date.<sup>150</sup>

One might argue that the ambulance chasing laws are permissible because the solicitation of clients by attorneys involves "pure commercial speech," and thus is entitled to less constitutional protection than the speech of those soliciting on behalf of nonprofit charities. My point here is not that the state can or should limit OPO agents from soliciting families of the deceased, but rather that the law commonly recognizes that bereaved individuals are so vulnerable to exploitation that they should be protected from those who would seek to turn a profit from their tragedy. Surely it cannot be the case that newly bereaved families need thirty days after a tragedy before they are able to protect themselves from solicitations by a plaintiff's attorney, but do not require any time at all before they can think critically about whether to give away their loved ones' tissue to a company. It is quite possible that the success of the OPO agents who solicit on behalf of both nonprofit and for-profit users of human tissue will be a

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147. See, e.g., *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) (upholding an attorney advertisement rule which prohibited attorneys from contacting accident victims for thirty days after the accident). The court determined that the rule withstood the three-pronged scrutiny test for restrictions on commercial speech protected under the First Amendment because the state bar had a substantial interest in protecting citizens from invasive conduct and the remedy for such invasiveness was narrow in scope and duration. *Id.* at 635. OPO agents are no more sympathetic than lawyers soliciting business from accident victims. Indeed, they are arguably less sympathetic. Clearly, we can regulate them; the only question is how best to do so.

148. See *Bates v. State Bar*, 433 U.S. 350 (1977).

149. *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 449 (1978) (citing *Bates*, 433 U.S. at 366).

150. *Id.* at 466. See also *Went For It*, 515 U.S. 618 (upholding Florida's ban on direct-mail solicitation of accident or disaster victims and their relatives during a thirty-day period following the accident or disaster). "The Bar asserts that it has a substantial interest in protecting the privacy and tranquility of personal injury victims and their loved ones against intrusive, unsolicited contact by lawyers." *Id.* at 624 (citing Brief of Petitioner at 25–27, *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995) (No. 94-226)).

reflection of the fact that the donors' families simply were not emotionally capable of behaving in a self-maximizing, or even a minimally self-protective manner.<sup>151</sup>

It is true, to be sure, that families in mourning engage in numerous business transactions in the immediate aftermath of death. They buy coffins, arrange for burial, hire an officiator, and contract for other funeral-related expenses. But they affirmatively seek out these contracts, choosing which companies to approach, when to approach them, and deciding on their own which services to procure.<sup>152</sup> By contrast, the tissue solicitation "opportunity" comes to them within hours of death, often in-person and at the hospital or in their homes.

If families agree to make donations of tissue to the for-profit tissue industry, one must consider the likelihood that they do so because they are in pain and distracted at the time of solicitation. It would seem that this problem is an insoluble one, as the tissue transplantation industry must obtain its raw material during the first twenty-four hours after death.<sup>153</sup> In the following section, I propose two solutions that would minimize, if not altogether alleviate, the problem of family vulnerability in the solicitation of human tissue.

## VI. SOLUTIONS

If the government is interested in supporting participants in the organ and tissue transplantation system as a whole, as well as all those involved in the broader market in human tissue, the government has no choice but to craft more sensitive regulations governing the process of tissue solicitation. The problems identified in the preceding sections all speak to the need to separate the solicitation process from the immediate aftermath of death, with its attendant emotionality and vulnerability. If this is not feasible, then the government should attempt to regulate the market in human tissue by permitting donors or their families to be compensated at fixed rates for their donations. In the paragraphs below, I briefly sketch out both of these proposals.

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151. It is also possible that the family understands the nature of the solicitation and is comfortable supporting the industry. This may be particularly true in the event that the law continues to ban payment for human tissue, thereby reducing the family's options to two: giving the tissue to the company, knowing that some good will come of it, or refusing to give altogether.

152. It is worth noting that the funeral industry is regulated by federal and state law in order to protect vulnerable buyers from exploitation. See, e.g., Funeral Industry Practices, 16 C.F.R. § 453.2 (2003) (requiring that sellers make a number of pre-sale disclosures to buyers). For a comprehensive review of the federal regulation of the funeral industry, see David E. Harrington & Kathy J. Krynski, *The Effect of State Funeral Regulations on Cremation Rates: Testing for Demand Inducement in Funeral Markets*, 45 J.L. & ECON. 199 (2002).

153. See Belli, *supra* note 9.

*A. Tissue Solicitation Prior to Death*

Most of the problems discussed in previous sections exist only because of the difficulty of asking newly bereaved family members to make a decision about donating tissue within twenty-four hours of their loved one's death. This problem could be alleviated were there a mechanism for conducting this solicitation ahead of time, by asking competent individuals to declare their preferences regarding tissue donation.<sup>154</sup>

Such "advance directives" already exist with regard to organ donation. States typically facilitate the creation of a record of an individual's intent by the use of donor cards or driver's license check-off provisions.<sup>155</sup> Although state laws vary in the extent to which these advance directives are considered binding or merely indicative of the deceased's intent with regard to donation, there is little doubt that this evidence helps to generate awareness of the possibility of organ donation upon death.<sup>156</sup> As a result, these mechanisms reduce the uncertainty and vulnerability of surviving family members asked to make a quick decision about donation following death.

These mechanisms could be expanded to encompass the possibility of tissue donation or, if compensation were to be permitted, of payment. Soliciting the participation of prospective tissue donors before death would eliminate the risks inherent in attempting to inform families and then solicit donations or strike bargains with them in the first twenty-four hours after death. Instead, individuals would be alerted to the existence of the industry, and they presumably would have time to make an independent investigation into the merits of the industry. The solicitation process would, of necessity, be more educational in nature, as there would be little sense of urgency in attempting to secure a specific recovery. The organ and tissue transplantation system would be insulated from the problem of spillover harm due to the need to explain the profit-making arm of the industry in great detail to a mourning family. In all, there would seem to be little downside to implementing procedures for soliciting tissue from individuals prior to death, particularly to the extent that such solicitation is removed from the healthcare setting, and thus, from the risk that a patient might feel

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154. I am grateful to Mike Newdow, doctor, lawyer, and professional atheist, for thinking through this problem with me, and for suggesting this solution.

155. See Sheldon F. Kurtz & Michael J. Saks, *The Transplant Paradox: Overwhelming Public Support for Organ Donation vs. Under-Supply of Organs: The Iowa Organ Procurement Study*, 21 J. CORP. L. 767, 788 (1996).

156. See *id.*

that his or her treatment will be affected by the decision of whether to donate tissue.

*B. Protecting Families in Post-Mortem Solicitations: The Need for Set Rates of Compensation*

As we have learned from the experience of efforts to increase organ donation via donor cards and driver's license check-off options, it is impossible to reach all members of society with this information.<sup>157</sup> Even with a system for securing tissue donation intentions prior to death, there still will be a need for solicitation of human tissue from surviving family members. If this is to occur, then we must be mindful of the problems identified in the preceding section of this Article.

Unfortunately, the problems identified appear to suggest solutions that are, at best, inconsistent. For instance, in order to ensure that families are fully informed about the nature of the donation they are being asked to make, an extremely detailed disclosure must be made. At the same time, sensitivity to the context in which these solicitations are made would seem to militate against a long, involved solicitation process. Add to this the concern about the impact of disclosure on the viability of both the nonprofit and the for-profit sectors of the human tissue industry, and it would seem that OPO agents have little choice but to launch into an extended monologue, despite the fact that this will do little to educate or protect families in their time of grief.

One way to reduce the risk of overreaching during the solicitation process is to involve disinterested parties in the solicitation.<sup>158</sup> Were the families to be represented by truly neutral "family advocates," for instance, one might worry less about them being pressured into making donations. Of course, it might be challenging to ensure the long-term neutrality of such advocates, particularly if they were employed by the institutions that care for the dying, let alone if they were paid by the transplantation industry.

To my mind, the most efficient way around the many problems associated with the solicitation of tissue is to eliminate the gift or bargain aspect of these transactions by establishing set rates of compensation to be tendered in exchange for human tissue. This might be accomplished in a variety of manners and need not trigger

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157. *Id.* at 783 (arguing that drivers license check-off provisions and donor cards do not sufficiently reach the donor pool and pointing to the fact that "[o]nly 43% of those generally supporting the donation of organs for transplantation have an appropriate mark on their driver's license").

158. I am indebted to Josh Shepton, Stanford Law School, Class of 2008, for developing this idea.

the advent of direct compensation to family members.<sup>159</sup> For example, the law might require tissue recipients to donate, on a per ounce basis, a fixed amount of their revenues to tissue-related charities. Skin donations might generate donations to charities that support burn victims. If the law is concerned with maintaining and reinforcing the line between the for-profit and the nonprofit industries dealing with human tissue, the for-profit recipients might also be required to contribute a percentage of their profits to specified nonprofit, transplant-related entities.

I am less interested in determining the precise amount of the donation or compensation than I am in the ways in which this approach resolves so many of the tensions discussed above. By acknowledging the value of the raw material without which the human tissue industry could not exist, this approach is more honest than the current system, in which the donors are the only participants in the tissue industry who do not share in the economic benefits it generates. Justice and fairness are further enhanced by requiring those who benefit from tissue donations, regardless of whether they are nominally structured as for-profit or nonprofit entities, to pay something for their raw material. By setting rates of compensation, the family need not be subjected to a long solicitation process for which they are ill-equipped to negotiate in their own self-interest. And by embracing a sense of fairness, there is less risk that families will perceive the tissue and organ industry as tarnished and refuse to donate altogether.

Because of the time-sensitive nature of the retrieval process for human tissue and organs, there is no way to completely insulate vulnerable family members from the “ambulance chasing” problems inherent in the solicitation process. Offering families either compensation at a set rate or the possibility of generating revenue for a chosen charity does redress many of the most problematic aspects of the solicitation process. The family is not asked to make a gift to a for-profit industry, nor is it required to negotiate the sale of their loved ones’ “raw material.” It would seem that the only remaining reason why the family would need to be informed about the distinctions between nonprofit and for-profit end-uses of tissue would in-

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159. The offer of a fixed rate of compensation to family members in exchange for tissue would not be unprecedented. For example, consider the former practice of the University of Michigan hospital, which recognized the value it was deriving from the sale of discarded placentas to downstream users by offering new mothers a minor rebate (twenty dollars) on their hospital bills in exchange for their permission to use the placenta. This practice was discontinued when federal regulations on tissue banking foreclosed the practice of selling tissue. Telephone Interview with Edward Goldman, *supra* note 28.

volve their right to object to the use of their loved ones' tissue for cosmetic surgery.

## VII. CONCLUSION

It took decades for the federal government to acknowledge and attempt to prevent the predatory practices of some within the human tissue industry. It is clear that the proposed regulations fall short of their aim of shielding grieving families from the potentially exploitative aspects of tissue solicitation. Moreover, as promulgated, these regulations may have the unintended effect of curtailing or limiting the available supply of transplantable organs and tissue. These problems can be minimized first by endeavoring to solicit tissue from competent individuals prior to death and second by offering some form of compensation to families who agree to donate their loved ones' tissue.

To be sure, there are risks inherent in injecting the possibility of donor compensation into the market in human tissue. As ethicist Dr. Joel Frader remarked, "Capitalism can't solve the problem of grief and grief may render capitalism even more problematic and ugly than it already is."<sup>160</sup> I believe that these risks can be cabined and are, in any event, offset by the countervailing risks posed by the present system both to families and to the entire organ and tissue industry. Ultimately, the government has the moral and legal obligation to regulate the market in human tissue by setting boundaries that preserve human dignity as well as faith in the organ and tissue industry.

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160. Telephone Interview with Joel Frader, *supra* note 132.



